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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,571	11/20/2003	Volker Schellenberger	GC560-D1-C1	3420
7590	03/24/2005		EXAMINER	
Genencor International, Inc. 925 Page Mill Road Palo Alto, CA 94034-1013			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/719,571	SCHELLENBERGER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Maria B. Marvich, PhD	1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 17 December 2004.

2a)  This action is FINAL.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 49-54 and 56-71 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 49,52-54,56,57,59,61-64,68,70 and 71 is/are rejected.

7)  Claim(s) 50,51,58,60, 65-67 and 69 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 20 November 2003 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

**DETAILED ACTION**

This office action is in response to an amendment filed 12/17/04. Claims 1-48 and 55 have been canceled. Claims 49 and 56 have been amended. Claims 49-54 and 56-71 are pending.

***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicants' amendment and therefore, this action is not final.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no literal support in the originally filed specification for the claimed methods recited in the pending claims for a method of isolating a protein. The specification teaches methods of evolving a microorganism and methods of transforming the microorganism with a nucleic acid. However, methods of isolating a protein expressed by the cell are not taught.

Applicant submitted a preliminary amendment on the filing date of the instant application comprising the pending claims and recited subject matter. Therefore, the pending claims do not constitute new matter. It is necessary, however, for applicant to amend the instant specification to provide antecedent support for the subject matter recited in the pending claims. Care should

be taken to limit what is incorporated into the specification to that which is recited in the claims submitted in the preliminary amendment submitted on 11/20/03.

### ***Priority***

In the reference to the prior application inserted, as the first sentence of the specification of this application, the current status of all nonprovisional parent applications referenced should be updated. Specifically, U.S. Serial No. 09/079,750, filed 10/23/01, is now U.S. Patent No. 6,705,503.

Claim 51 and 66 recite the step of isolating at least one heterologous protein from the evolved microorganism, which is not found in the priority documents. Therefore, a priority date of 11/20/03 will be attributed to these limitations.

### ***Claim Objections***

Claim 50 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 49 has been amended to recite that the evolved microorganism expresses the heterologous protein while claim 50 recites that the protein is expressed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 49 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims3 of U.S. Patent No. 6,365,410. **This rejection is maintained for reasons of record in the office action mailed 8/24/04.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in 6,365,410. That is, the cited claims of 6,365,410 anticipate and fall entirely within the scope of the rejected claims of the instant application. Both the claim in the 6,365,410 patent and the instant claims 49, 56, 58-61, 67-68 and 70 recite the exact same method steps. However, the claims differ in that claims 1-10 in the 6,705,503 recites in the preamble that the method is directed to preparation of an evolved microorganism whereas the claims in the instant application recite in the preamble that the method is for producing a protein. Additionally, claim 3 cannot be considered patentably distinct over claim 49 or claim 55 because it would have been obvious to one of ordinary skill to modify the method of claim 3 from patent 6,329,176 by also reciting that the microorganism to be cultured is also obtained to thus generate the instant invention. The ordinary skilled artisan would have been motivated to do this as the embodiment of also obtaining a microorganism is essential to the invention and the invention cannot be performed without also obtaining a microorganism. Given the teachings of the claims in

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6,365,410 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for evolved microorganism production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,365,410 patent, then two different assignees would hold a patent to the claimed invention of 6,365,410, and thus improperly there would be possible harassment by multiple assignees.

Claim 49, 52-54, 56, 57, 59, 61-64, 68 , 70 and 71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,705,503. **This rejection is maintained for reasons of record in the office action mailed 8/24/04 and upon reconsideration has been extended to claims 68, 70 and 71.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in 6,705,503. That is, the cited claims of 6,705,503 anticipate and fall entirely within the scope of the rejected claims of the instant application. Both the claim in the 6,705,503 patent and the instant claims recite the exact same method steps. However, the claims differ in that claims 1-10 in the 6,705,503 recites in the preamble that the method is directed to preparation of an evolved microorganism whereas the claims in the instant application recite in the preamble that the method is for producing a protein.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,705,503 patent, then two different assignees

would hold a patent to the claimed invention of 6,705,503, and thus improperly there would be possible harassment by multiple assignees.

***Response to Argument***

Applicants' statement that upon notification of allowance a terminal disclaimer will be submitted on page 8 of the amendment filed 12/27/04 is acknowledged. However, until the recited claims are patented or a terminal disclaimer is filed, the claims remain rejected.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 71 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 71 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

The instant invention recites a genus of mutator genes selected from the group consisting of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS* and *mutU* mutations or homologues thereof.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants teach that a mutator gene is a DNA repair gene with a mutation. For the development of evolved microorganisms, applicants generate sixteen plasmids comprising mutations in *mutD* (see table 1). These plasmids are used to transform target organism and are further exposed to conditions that generate evolved microorganisms. With the exception of the nucleic acid and amino acid sequences for *mutD*, the specification does not disclose any of the sequences of the recited genes nor provide a description of the genes such that the structural requirements of the genes can be envisioned. The prior art does not teach structural analysis of the recited genes. Applicants have not clearly identified the genes that belong to this genus except by disclosing that a homologue refers to a functionally related DNA repair gene (page 7, line 16). Neither the prior art nor the specification has provided adequate written description to support or illustrate the genus encompassed by the claim. Given the absence of disclosed or art recognized correlations between structure and function of homologues of *mut* genes, the large number of potential homologues that can be generated in said genes and the uncertainty that any homologue will be functional, it must be considered that any homologue must be empirically determined. By disclosing *mutD* mutations, the applicants have not reduced to practice homologues of *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU*

mutations. Given the diversity of the recited mutator genes, the absence of disclosed or art recognized structure-function relationships and the unpredictability of the art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

Claim 61 is vague and indefinite in that the metes and bounds of “a method for producing a protein”. The method as recited does not set forth any steps for the production of a protein.

Claim 71 is vague and indefinite in that the metes and bounds of “the mutator gene” are unclear. The mutator gene is selected from the group consisting of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS* and *mutU* mutations. As recited, *mutU* alone encompasses a mutation whereas the remainder of the genes listed encodes wild type DNA repair proteins. Therefore, it is unclear how *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL* and *mutS* genes can be mutator genes.

### ***Conclusion***

Claims 49, 52-54, 56, 57, 59, 61-64, 68, 70 and 71 are rejected.

Claim 50 is objected to for minor informalities.

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Claims 51, 58, 60 and 65-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**GERRY LEFFERS**  
PRIMARY EXAMINER

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

March 8, 2005